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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,084	03/07/2002	Clarence Webster Andrews III	PU3517USW	7283

23347 7590 12/16/2004

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EXAMINER

RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/070,084

**Applicant(s)**

ANDREWS ET AL.

**Examiner**

Deepak Rao

**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-7, 9-16, 18-23, 25, 26, 28-30, 34-36, 40 and 43-62 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) 15, 16, 21 and 22 ~~is/are~~ are withdrawn from consideration.
- 5) ☒ Claim(s) 2-7, 9-14, 18-20, 23, 25, 26, 28, 29, 34-36, 40, 43-51 and 54-62 ~~is/are~~ are allowed.
- 6) ☒ Claim(s) 30, 52 and 53 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This office action is in response to the amendment filed on July 28, 2004.

Claims 2-7, 9-16, 18-23, 25-26, 28-30, 34-36, 40 and 43-62 are pending in this application.

#### ***Election/Restrictions***

This application contains claims 15-16 and 21-22 drawn to an invention nonelected with traverse in Paper No. 11102003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

#### ***Withdrawn Rejections/Objections:***

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

#### ***The following rejections are maintained:***

Claims 30, 52 and 53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of infection by HIV by inhibition of HIV reverse transcriptase, does not reasonably provide enablement for prevention of infection by HIV. The specification does not enable any person skilled in the art to which it pertains, or with

Art Unit: 1624

which it is most nearly connected, to use the invention commensurate in scope with these claims.

The reasons provided in the previous office action are incorporated hereby reference.

Applicant's arguments filed on July 28, 2004 have been fully considered but they were not deemed to be persuasive. Applicant relies on the specification and the 'prescribing information' of Retrovir® argues that 'HIV reverse transcriptase inhibitors may be used to prevent HIV infection'. As indicated in the previous office action, the specification provides test assay and procedure to determine the activity of the compounds as HIV-1 Reverse transcriptase inhibitors. The prescribing information of Retrovir® provides the administration of the agent for the 'treatment of HIV infection'. Applicant specifically emphasized that "Retrovir® is indicated for the prevention of maternal-fetal transmission", however, the reference clearly provides that "The efficacy of this regimen for preventing HIV transmission .... has not been evaluated".

The evidence presented in this case does not show such utilities related to 'prevention', but only warrants further study. Since the art does not disclose any chemotherapeutic **preventive** agents for the 'conditions' of the instant claims, the skilled artisan would not predict, in the absence of proof to the contrary, that the active agent(s) instantly claimed are efficacious in preventing the claimed disorders. The assertion of a broad application as set forth in the instant claims necessarily requires evidence to support applicant's asserted methods. The examiner notes there are no known pharmaceutical agents recognized as **preventive** agents for the conditions claimed, and one of skill in this art could not predict, from the evidence of record, that the active agents asserted to be useful in the instantly claimed method, can indeed prevent HIV infection.

Art Unit: 1624

The examiner notes, there is not seen sufficient guidance provided in the form of administrative profiles, combination ratios of the active agents or references to same in the prior art to provide the skilled artisan with sufficient guidance to practice the instant preventive method. **Prevention** is seen to encompass administering the active agent to a baby or small child or healthy adult with the expectation that the subject would not be afflicted with the disease or condition. The data and evidence provided in the instant disclosure leads the examiner to doubt the objective truth of assertions of prevention of HIV infection. A conclusion of lack of enablement means that, based on the evidence regarding each of the *Wands* factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). There is not seen in the disclosure, sufficient evidence to support applicant's claims of prevention. There is not seen sufficient working examples or data from references of the prior art providing a nexus between that which applicant asserts as proof of a method for preventing HIV infection or extrapolation from the data and evidence currently provided on the record to support methods drawn to preventing the same.

The diagnosis of each of the disease is generally suggested by medical history and reports of endoscopy, cytology, X-ray, biopsy, etc. depending on the symptoms, signs and complications, which is essential to establish the dosage regimen for appropriate treatment or prevention. The disclosure does not provide any guidance towards the dosage regimen required to facilitate the prevention of HIV infection generally, nor indicate competent technical references in the appropriate method of preventing.

Art Unit: 1624

***Allowable Subject Matter***

Claims 2-7, 9-14, 18-20, 23, 25-26, 28-29, 34-36, 40, 43-51 and 54-62 are allowed. The references of record do not teach or fairly suggest the claimed compounds.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

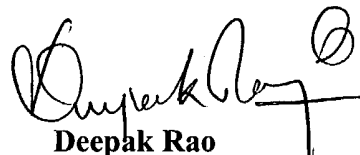
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (571) 262-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at (571) 272-

Art Unit: 1624

0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**Deepak Rao**  
**Primary Examiner**  
**Art Unit 1624**

December 13, 2004